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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAGOPIAN, CASEY SHEA	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/632,413	RICHARD ET AL.	
	Examiner	Art Unit	
	Casey Hagopian	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) *7-10,15 and 16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,11-14 and 17-21* is/are rejected.

7)☒ Claim(s) *6 and 22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt is acknowledged of applicant's Amendment/Remarks filed 7/27/2006. Claims 1-22 are currently pending. Claims 7-10, 15 and 16 have been withdrawn.

Response to Arguments

2. Applicant's arguments, see page 6, filed 7/27/2006, with respect to the objection of claim 5 have been fully considered and are persuasive. The amendment to claim 5 renders the objection moot, thus the objection has been withdrawn.

3. Applicant's arguments, see pages 6-7, filed 7/27/2006, with respect to the rejection under 35 USC 112 have been fully considered and are persuasive. The rejection of claims 1-5, 11-14 and 17-19 under 35 USC 112 has been withdrawn.

Applicant's arguments filed 7/27/2006 in regards to the rejection under 35 USC 102 have been fully considered and are persuasive. The rejection of claims 1-6, 12 and 14 under 35 USC 102 has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made (see New Rejections section of the rejection).

NEW REJECTIONS

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1-5, 11, 13, 14, 18 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Hariharan et al. (USPN 5,916,968). Hariharan discloses graft copolymers used as drug delivery devices comprising a backbone containing copolymerized acrylic acid and optionally, vinyl monomers, and side chains preferably containing polymers from the classes of polybutylene, poly(ethyleneoxide/propyleneoxide), polycaprolactum, polysaccharide, and polyamide polymers (abstract; column 2, lines 34-50). Hariharan specifies that an active medicament is contained in the drug delivery devices, specifically in the same polymeric layer, and also some advantages of the copolymer materials used in terms of drug loading (column1, lines 47-50; column 9, lines 20-22). Hariharan specifically discloses that the acrylic/vinyl polymeric backbone has a glass transition (Tg) of -30°C or lower (i.e., a "low Tg" or rubbery phase) (column 2, lines 59-61) and exemplifies various backbone polymer formulations having Tg's of no more than -38°C (column 7, lines 15-45). Hariharan further discloses specific polymers suitable for grafting onto the backbone (i.e. side chain polymers) including poly(vinyl chloride), poly(n-vinyl pyrrolidone) and poly(acrylamide) (column 4, lines 25-39); all of which posses a Tg of 50°C or higher (i.e., a "high Tg" or hard phase). Applicant's specification particularly points out that vinyl chloride has a Tg of 81°C, vinyl pyrrolidone has a Tg of 54°C and acrylamide has a Tg of 165°C (paragraphs 0040 and 0043). It should be noted that the examiner has adapted the position that the limitations "implantable" and "insertable" in describing the medical device in the instant claims is considered an intended use. The instant claims are product claims and any intended use recitation does not alone show

patentable distinction; there must be a structural difference between the claimed invention and the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim. Similarly, the limitation, "is adapted for", found in claims 18 and 20, is also being treated as an intended use recitation. Structurally, said claims do not impart any additional limitations, thereby lacking any demonstration of patentable distinction between the prior art and the claimed invention. It should be further noted that the limitation "said graft copolymer has an elongation at break of at least 25% at ambient temperature" (claim 11) is considered a dependent property of the particular materials used. A product and its materials are inseparable and as such it is the position of the examiner that since Hariharan teaches the materials of claim 1, the materials also posses the particular dependent property "an elongation at break of at least 25% at ambient temperature". It should be also noted that claim 13 is deemed a product-by-process claim due to the limitation, "is sterilized using a quantity of radiation effective to kill pathogens" and as such, determination of patentability is based on the product itself, not by the method in which it is made. The claim does not further limit the product itself. Thus it is for these reasons that the disclosures of Hariharan render the instant claims anticipated.

6. Claims 1, 2, 11-14 and 17-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Kronfli et al. (GB 2271717 A). Kronfli discloses polymeric biochemical compositions, particularly for medial uses, comprising a graft copolymer prepared via irradiation and one or more pharmaceutical compounds (abstract). The preferred copolymer is ethylene-vinyl acetate polymer grafted with acrylic and/or methacrylic acid

(abstract). Poly(ethylene-vinyl acetate) has a Tg of -7°C (i.e. rubbery phase) as evidenced by PolySciences, Inc. and acrylic and methacrylic acids have a Tg of 105°C and 228°C (i.e. glassy phase), respectively, as indicated in applicant's specification (paragraphs 0042 and 0043). Kronfli discloses that the compositions act as a polymeric reservoir for the rate controlled release of the pharmaceutical compound(s) (abstract). Kronfli further discloses medical devices including transdermal delivery reservoirs, ocular inserts, subcutaneous implants, catheters, and so on as well as particular pharmaceuticals including non-steroidal anti-inflammatories and cardio-vascular treatments (page 6, lines 16-25). Kronfli also discloses the addition of additives and enhancing agents including polyalkylene glycols (page 1, lines 24-25; page 5, lines 7-15). It should be noted that the examiner has adapted the position that the limitations "implantable" and "insertable" in describing the medical device in the instant claims is considered an intended use. The instant claims are product claims and any intended use recitation does not alone show patentable distinction; there must be a structural difference between the claimed invention and the prior art. In other words, if the prior art structure is capable of performing the intended use, then it meets the claim. Similarly, the limitation, "is adapted for", found in claims 18 and 20, is also being treated as an intended use recitation. Structurally, said claims do not impart any additional limitations, thereby lacking any demonstration of patentable distinction between the prior art and the claimed invention. It should be further noted that the limitation "said graft copolymer has an elongation at break of at least 25% at ambient temperature" (claim 11) is considered a dependent property of the particular materials used. A

product and its materials are inseparable and as such it is the position of the examiner that since Kronfli teaches the materials of claim 1, the materials also posses the particular dependent property "an elongation at break of at least 25% at ambient temperature". It should be also noted that claim 13 is deemed a product-by-process claim due to the limitation, "is sterilized using a quantity of radiation effective to kill pathogens" and as such, determination of patentability is based on the product itself, not by the method in which it is made. The claim does not further limit the product itself. Thus it is for these reasons that the disclosures of Kronfli render the instant claims anticipated.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 1-5, 11, 13, 14, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hariharan et al. (USPN 5,916,968). Hariharan includes the elements discussed above in paragraph 6 of the rejection. However, Hariharan is silent to grafting polymers specifically having a high Tg, i.e. glassy phase. As discussed earlier, Hariharan teaches particular grafting polymers that possess a high Tg (e.g. poly(vinyl chloride), poly(n-vinyl pyrrolidone) and poly(acrylamide)), although it is not required. One of one of ordinary skill in the art would have been motivated to include grafting polymers particularly having a high Tg because Hariharan teaches that "Specific grafted polymers will depend on the specific enhancers used in a particular drug delivery or would dressing system inasmuch as different enhancers will present different solubility consideration for the adhesives" (column 2, lines 47-51). Furthermore, the intended use will dictate what polymers will be employed in the final product. One of ordinary skill in the relevant art would reasonably expect a drug delivery device comprising a graft copolymer comprising a backbone and side chains, wherein the backbone possesses a low Tg and the side chains possess a high Tg depending on what enhancers are employed as well as the intended use of the device. Thus, in Hariharan, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include grafting polymers that possess a high Tg such as poly(acrylamide).

Pertinent Art

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Chen et al. (US 2003/0039689 A1) teaches a polymer-based, sustained release drug delivery system (title; abstract). Chen specifically exemplifies a

coating comprising a poly(ethyl acrylate and methyl methacrylate) copolymer and 5-fluoouracil, an anti-neoplastic drug (example 9). Chen further teaches that the coatings may be applied to medical devices including catheters vascular grafts and stents (paragraphs 0037-0038).

Allowable Subject Matter

11. Claims 6 and 22 are objected to as being dependent upon a rejected base claim, but may be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

12. Claims 1-5, 11-14 and 17-21 have been rejected. Claims 6 and 22 are objected to. No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Tuesday through Friday from 8:00 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Casey Hagopian

Casey Hagopian
Examiner
Art Unit 1615

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